August 17, 2018

B.T.I. Biotechnology Institute, S.L.
Fernanda Ros
Regulatory Affairs Manager
Leonardo Da Vinci 14, Parque Tecnologico De Alava
Minano, 01510
SPAIN

Re: K173257
Trade/Device Name: BTI Dental Implant System UnicCa®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 16, 2018
Received: July 18, 2018

Dear Fernanda Ros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173257

Device Name
BTI Dental Implant System UnicCa®

Indications for Use *(Describe)*

The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function.

In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations.

In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY
K173257

I. SUBMITTER

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Date Prepared: August 16, 2018

II. DEVICE

Name of Device: BTI Dental Implant System UnicCa®
Common or Usual Name: Root-form Endosseous Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class: II
Product Code: DZE

III. PREDICATE DEVICE

The primary predicate device is BTI Dental Implant System UnicCa®, K151391, concurrence date: May 2nd, 2016.

Reference predicates are identified that encompass similar larger diameter/longer length dental implants proposed for the subject UnicCa® device. The reference predicates include the NobelActive ® Interna Hex (Nobel Biocare AB – reference K142260 cleared on May 11, 2015) and the Biomet OSSEOTITE II Internal Hex (Biomet 3i – reference K100724 cleared on April 1, 2011)

IV. DEVICE DESCRIPTION

The BTI Dental Implant System UnicCa® is a self-tapping, threaded, root form dental titanium implant provided with two types of connections; external (i.e., Externa®) and internal (i.e., Interna®), in a variety of platforms and range of diameters (3.0 – 6.0 mm) and lengths (5.5 – 18.0 mm). BTI Dental Implant System UnicCa® features an implant surface treatment that improves the hydrophilicity of the implant.

The purpose of this 510(k) is to allow B.T.I. to expand the product offering for the Wide and Universal Plus 5.5 mm and 6.0 mm diameter Interna® implants to extend implant length up to 15 mm. Specifically, the implants described within this submission are summarized in **Table 5-1**.

Table 5-1. Overview of size range extension of BTI Dental Implant System UnicCa® Interna® implant, platforms, diameters and lengths:

Connection	Platform	Diameter (mm)	Length (mm)
Interna®	Wide	5.5	7.5 / 8.5 / 10 / 11.5 / 13 / 15
		6.0	7.5 / 8.5 / 10 / 11.5 / 13
	Universal Plus	5.5	7.5 / 8.5 / 10 / 11.5 / 13

The modifications described herein do not alter the overall design of the BTI Dental Implant System UnicCa® or product intended use, nor do the changes alter the fundamental scientific technology. In addition, the material used, the energy type, environmental specifications, performance specifications, ergonomics of the patient-user interface, packaging and expiration dating, manufacturing and sterilization remains unchanged from the predicate device.

V. INDICATIONS FOR USE

The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function.

In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations.

In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

VI. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modified UnicCa® Interna® BTI Dental Implant Systems, have the following similarities to those which previously received 510(k) concurrence via K151391:

- have the same indication for use,
- use the same operating principle,
- incorporate the same basic implant design,
- incorporate the same materials,
- have the same surface treatment,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

The only modification consists of a dimensional change in the Interna® connection implants. Under the same basic implant design, the diameter is increased over lengths already cleared by K151391. **Table 5-2** represents diameters and lengths of the Interna® connection cleared within K151391 and the dental implants subject of this current Traditional 510(k) submission. Even if considered as a dimensional change, the additional size offerings described herein are within the range previously cleared for the BTI Dental Implant System UnicCa® (K151391). Therefore, it might be considered as a range extension of the already cleared BTI Dental Implant System UnicCa® (K151391).

Table 5-2. Range of platform, diameter and lengths of the predicate UnicCa® Interna® implant previously cleared within K151391 and additional size offerings subject of this 510(k) submission (new size offerings identified in bold text).

Connection	Platform	Diameter (mm)	Length (mm)
Interna®	Wide	5.0	6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
		5.5	5.5 / 6.5 / **7.5 / 8.5 / 10 / 11.5 / 13 / 15**
		6.0	5.5 / 6.5 / **7.5 / 8.5 / 10 / 11.5 / 13**
	Universal Plus	4.5	6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
		5.0	5.5 / 6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
		5.5	5.5 / 6.5 / **7.5 / 8.5 / 10 / 11.5 / 13**
	Universal	3.3	8.5 / 10 / 11.5 / 13 / 15
		3.5	7.5 / 8.5 / 10 / 11.5 / 13 / 15
		3.75	7.5 / 8.5 / 10 / 11.5 / 13 / 15
		4.0	7.5 / 8.5 / 10 / 11.5 / 13 / 15 / 18
		4.25	7.5 / 8.5 / 10 / 11.5 / 13 / 15

A comparison of the device features, indications for use, laboratory data and other information demonstrate that the modified BTI Dental Implant System UnicCa® Interna® implant is substantially equivalent to the predicate device. In the following pages, a comparison table has been provided, **Table 5-3**.

Table 5-3. Comparison of the modifed Interna® BTI Dental Implant System UnicCa® with predicate BTI Dental Implant System UnicCa®:

Characteristics	Subject Device / Current Submission	Predicate
	Modified BTI Dental Implant System UnicCa® Interna® Implant	**K151391, BTI Dental Implant System UnicCa®**
Indications for Use	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants areindicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors andmandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

Characteristics	Subject Device / Current Submission		Predicate
	Modified BTI Dental Implant System UnicCa® Interna® Implant		**K151391, BTI Dental Implant System UnicCa®**
Product Classification	Device Class II Regulation No.:21 CFR 872.3640. Product code: DZE; Endosseous dental implant		Device Class II Regulation No.:21 CFR 872.3640. Product code: DZE; Endosseous dental implant
Implant Design/Geometry	**.** Threaded, root form		Threaded, root form
Material	**.** Commercially pure titanium grade 4		Commercially pure titanium grade 4
Abutment Compatibility/ Connection	Internal (Interna)		Internal (Interna) and External (Externa)
Dimensions (mm)	Interna	Diameter: 5.5 and 6.0 Lengths: 7.5 to 15	Diameter: 3.3 to 6.0 Lengths: 5.5 to 18.0
	Externa	Not applicable	Diameter: 3.0 to 5.5 Lengths: 7.0 to 18.0
Roughness	Neck: Sq[1]= 0.7 ± 0.1 µm; Sdr[2]= 50± 10%		Neck: Sq[3]= 0.7 ± 0.1 µm; Sdr[4]= 50± 10%

[1] Sq: Root Square Mean Roughness.
[2] Sdr= Developped surface.

Characteristics		Subject Device / Current Submission	Predicate
		Modified BTI Dental Implant System UnicCa® Interna® Implant	**K151391, BTI Dental Implant System UnicCa®**
		Thread: Sq≥ 1.2 µm; Sdr≥ 200%	Thread: Sq≥ 1.2 µm; Sdr≥ 200%
		Valleys: Sq= 1.0 ± 0.2 µm; Sdr= 85± 15%	Valleys: Sq= 1.0 ± 0.2 µm; Sdr= 85± 15%
Mechanical Properties	**Material (Titanium)**	**.** In compliance with ISO 5832-2 and ASTM F67.	In compliance with ISO 5832-2 and ASTM F67.
	Fatigue	**.** Equivalent; platform (diameter and length) dependent.	Equivalent; platform (diameter and length) dependent.
Hydrophilicity		**.** Calcium surface treatment	Calcium surface treatment
Supplied Sterile		**.** Yes	Yes
Sterilization		**.** Gamma Radiation	Gamma Radiation
SAL		. 1 x 10^{-6}	1 x 10^{-6}
Packaging		**.** Unique container (vial with clamp)	Unique container (vial with clamp)
Shelf-Life		**.** 5 years (based on accelerated studies, 2 years real time data from on-going stability studies)	5 years (based on accelerated studies, 1 year real time data from on-going stability studies)

A comparison of the device dimensional characteristics and indications for use demonstrate that the modified BTI Dental Implant System UnicCa® Interna® implant is substantially equivalent to the NobelActive Interna Hex (Nobel Biocare AB) and Biomet OSSEOTITE II Internal Hex (Biomet 3). In the following pages, a comparison table has been provided, **Table 5-4**.

Table 5-4. Comparison of the modifed Interna® BTI Dental Implant System UnicCa® with reference predicate NobelActive Interna Hex (Nobel Biocare AB) and Biomet OSSEOTITE II Internal Hex (Biomet 3)

Characteristics	Subject Device / Current Submission	Reference Predicate	
	Modified BTI Dental Implant System UniCca® Interna® Implant	**K142260, NobelActive® Interna Hex**	**K100724, Biomet OSSEOTITE II Internal Hex**
Indications for Use	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.	BIOMET 3i Dental Implants are intended for surgical placement in either jaw and used for anchoring or supporting single- and multiple-unit prostheses. BIOMET 3i Dental Implants can be immediately loaded when primary stability and proper occlusion have been established.

Characteristics		Subject Device / Current Submission	Reference Predicate	
		Modified BTI Dental Implant System UniCca® Interna® Implant	**K142260, NobelActive® Interna Hex**	**K100724, Biomet OSSEOTITE II Internal Hex**
Dimensions (mm)	**Diameter**	5.5 and 6.0	3.0, 3.5, 4.3, 5.0, 5.5	3.25, 4.0, 5.0 and 6.0
	Lenght	7.5 to 15	7.0, 8.5, 10.0, 11.5, 13.0, 15.0 and 18.0	Ø 3.25: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0 Ø4.0: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0 Ø5.0: 8.5, 10.0, 11.5, 13.0, 15.0 Ø6.0: 8.5, 10.0, 11.5, 13.0, 15.0

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility was established within BTI Dental Implant System UnicCa® 510(k) K151391, in conformance with *ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* were performed. Sample preparation for testing was made based on ISO 10993-12:2012. As there have been no changes in the materials of manufacture compared with the predicate system, biocompatibility testing included within K151391 is directly applicable to the modified device subject of this submission.

Table 5-5. Biocompatibility Testing List:

Biocompatibility Testing		Standard
Implant	Cytotoxicity Test	ISO 10993-5:2009
	Delayed Hypersensitivity	ISO 10993-10:2010
	Intracutaneous Reactivity	ISO 10993-10:2010
	Acute Systemic Toxicity	ISO 10993-11:2006
Container	Cytotoxicity Test	ISO 10993-5:2009
Wetting Solution	Establishment of allowable limits for leachable substances	ISO 10993-17:2002

Bench Testing

Bench testing was presented within previous BTI Dental Implant System UnicCa® 510(k) K151391, to demonstrate that the devices met the required specifications for complete design verification tests, which included: Fatigue Testing based on EN ISO 14801:2008 (*Dentistry. Implants. Dynamic fatigue test for endosseous dental implants; ISO 14801:2007)*, Corrosion Testing, Surface Hydrophilicity TOF·SIMS Analysis, Packaging / Shelf-life Validation and Sterilization Evaluations. Based on risk analysis activities, previous testing performed encompasses the size range extension proposed for the Interna® implant as described within this current submission and therefore no additional bench testing has been performed.

Shelf life and package integrity to provide for an expiry of 5 years was validated previously within BTI Dental Implant System UnicCa® 510(k) K151391. This test was not repeated since all aspects of packaging and sterile barrier materials, process and process parameters are identical for all implants within the BTI Dental Implant System UnicCa® product family.

Sterilization validation successfully concluded that the gamma irradiation process, when performed per associated process specifications, can reliably sterilize the subject device to a SAL of 10^{-6}. Product integrity and characteristics are not affected by sterilization process, supporting the finding of substantial equivalence with predicate device. All aspects of the Gamma sterilization validation process and test remained unchanged as cleared under K151391.

Furthermore, the Limulus Amebocyte Lysate (LAL) bacterial endotoxin tests performed as per ANSI ST72, USP<85> and USP<161> on the subject device yielded a EU/Device value that was less than the established acceptance criteria of 20 EU/Device for medical devices not intended to contact cerebrospinal fluid.

Human Factors Study

A Human Factors study was performed to assess handling of the proposed a single-barrier packaging and users' ability to maintain sterility of the implant in aseptic field. The study concluded that the tested packaging is adequate for use in dental setting.

VIII. CONCLUSIONS

The comparison of similarities and differences between the modified device and the respective predicate devices demonstrate that the proposed and predicate devices are substantially equivalent.